guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application).

The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results. Only new information collections not already approved are included in the estimate in the following table. Quick reference instructions are a short version of the instructions that are written in simple language and that can be posted.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency of Response | Total Annual Responses | Hours per Response | Total Hours | Operating and Maintenance Costs |
|---|---|---|---|---|---|---|
| 493.15(a) and (b) | 40 | 1 | 40 | 780 | 31,200 | $50,200 |

[1] There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours | Operating and Maintenance Costs |
|---|---|---|---|---|---|---|
| 493.15(a) and (b) | 40 | 1 | 40 | 2,800 | 112,000 | $16,000 |

[1] There are no capital costs associated with this collection of information.

The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting. Based on previous years experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 112,000 hours.

The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000).

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 and § 809.10 have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437.

Dated: October 9, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–25177 Filed 10–19–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0490]**

### Draft Guidance for Industry and Food and Drug Administration Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications,'' dated October 2009. In this draft guidance, we refer to these products for hematopoietic reconstitution for specified indications as hematopoietic progenitor cells, cord (HPC–C). This draft guidance provides advice to potential sponsors (e.g., generally cord blood banks, or registries, and individual physicians serving as sponsor-investigators) to assist in the submission of an IND for certain HPC–Cs, when such HPC–Cs are not licensed in accordance with certain FDA regulations, and when a suitable human leukocyte antigen (HLA) matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition and there is no satisfactory alternative treatment. This draft guidance document is applicable only to HPC–Cs intended for hematopoietic reconstitution in patients with the clinical indications listed in the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' (HPC–C licensure guidance), published elsewhere in this issue of the **Federal Register**. FDA is also announcing that it no longer intends to exercise enforcement discretion with respect to the IND and biologics license application (BLA) requirements for minimally manipulated, unrelated allogeneic hematopoietic stem/progenitor cell products and the phase-in implementation period for IND and license application requirements will end as of October 20, 2011.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by January 19, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications,'' dated October 2009. This draft guidance provides advice to potential sponsors (e.g., generally cord blood banks, or registries, and individual physicians serving as sponsor-investigators), to assist in the submission of an IND for certain HPC–Cs, when such HPC–Cs are not licensed in accordance with 21 CFR part 601, and when a suitable HLA matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition and there is no satisfactory alternative treatment. This draft guidance document is applicable only to HPC–Cs intended for hematopoietic reconstitution in patients with the clinical indications as listed in the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Specified Indications'' (HPC–C licensure guidance), published elsewhere in this issue of the **Federal Register**.

FDA is also announcing that it no longer intends to exercise enforcement discretion with respect to IND and BLA requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products and the phase-in implementation period for IND and license application requirements for these products will end (see the **SUMMARY** for the ending date). We encourage sponsors to send in applications as soon as possible to allow sufficient time for review, comment, and resubmission as needed to complete all actions by the end of this 2-year period.

In the **Federal Register** notice of January 20, 1998 (63 FR 2985), FDA requested submission of comments proposing establishment controls, process controls, and product standards designed to ensure the safety and effectiveness of minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products derived from peripheral and cord blood for hematopoietic reconstitution. Also, in the January 20, 1998, notice, FDA announced its intention to phase in implementation of IND and license application requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products to permit the development of licensing standards for those products where possible.

In the **Federal Register** notice of January 17, 2007 (72 FR 1999), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies,'' dated December 2006. FDA received comments on the December 2006 draft guidance and those comments were considered as the guidance was finalized. The HPC–C licensure guidance finalizes the December 2006 draft guidance. Some of the comments received by FDA expressed the importance of access and availability of HPC–C products that do not meet the standards for licensure and therefore, cannot be licensed. FDA recognizes the importance of providing guidance for such products and is publishing this IND draft guidance for comment. The HPC–C licensure guidance document is effective on its date of publication.

This draft guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance when finalized will represent FDA's current thinking on these topics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches may be used if such approaches satisfy the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910–0014; 21 CFR part 1271 have been approved under OMB Control Nos. 0910–0559, 0910–0469, and 0910–0543; and FDA Form 1571 has been approved under OMB Control No. 0910–0014.

## III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may still, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

Dated: October 14, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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